K070359

510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

MAR 06 2007

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Rhonda Myer Regulatory Affairs Telephone: (574) 371-4927 Facsimile: (574) 371-4987 Electronic Mail: Rmyer7@dpyus.jnj.com
DATE PREPARED:	January 31, 2007
PROPRIETARY NAME:	ASR™ Hip Taper Sleeve Adapter
COMMON NAME:	Femoral Hip Prosthesis
CLASSIFICATION:	Class III device per 21 CFR 888.3330: Hip Joint metal/metal semiconstrained, with an uncemented acetabular component prosthesis
DEVICE PRODUCT CODE:	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy ASR™ Modular Acetabular Cup System, K040627 DePuy Ultima Unipolar Head and Sleeve Adapters, K965156

DEVICE DESCRIPTION:

The DePuy ASR Taper Sleeve Adapter mates with the ASR Femoral Heads (K040627) and any 11/13 or 12/14 DePuy femoral stem to provide differing offsets to best match the patient's anatomy.

INTENDED USE AND INDICATIONS:

Intended Use:

The subject taper sleeve adapters mate the femoral head to the femoral stem. This allows for a reduced number of femoral head components and offers various femoral head offsets and compatibility with multiple femoral stems. The subject device mates with all existing DePuy 11/13 and 12/14 stems.

Indications for Use:
The DePuy ASR™ Modular Acetabular Cup System is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The substantial equivalence of the ASR Taper Sleeve Adapter is shown by its similarity in intended use, indications for use, materials and design to the existing DePuy ASR™ Modular Acetabular Cup System Sleeve Adapters, K040627 and the DePuy Ultima Unipolar Head and Sleeve Adapters, K965156.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc
% Ms. Rhonda Myer
Regulatory Associate, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46582

MAR 06 2007

Re: K070359
Trade/Device Name: ASR™ Hip Taper Sleeve Adapter
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip Joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis
Regulatory Class: III
Product Code: KWA
Dated: February 6, 2007
Received: February 7, 2007

Dear Ms. Myer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DePuy
a Johnson & Johnson company

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, IN 46581-0988
USA
Tel: +1 (574) 267 8143
Fax: +1 (574) 371 4950

Indications for Use Statement

510 (k) Number (if known): K070359

Device Name: **DePuy ASR™ Taper Sleeve Adapter**

Indications for Use:

The DePuy ASR™ Modular Acetabular Cup System is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070359